K020524

MAR 2 0 2002

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR 807.92.

Submitter's Name:	GE Medical Systems Information Technologies
Submitter's Address:	15222 Del Amo Avenue Tustin, CA 92780
Telephone :	(800) 888-0777
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Contact Person:	Diana M. Thorson
Date Prepared:	January 14, 2002
Device Trade Name:	PatientNet™ Monitoring System
Device Classification Name:	System, Network and Communication, Physiological Monitors
Device Classification:	Class II
Predicate Device(s):	VitalCom Networked Monitoring System K962473

Device Description:
The modified PatientNet™ Monitoring System performs patient monitoring using PatientNet™ ambulatory radio transmitters or radio transmitters connected directly to bedside monitors or other digital bedside monitors with similar physiological parameters, and to ventilators that have digital outputs.

Intended Use:
The PatientNet™ System is intended to collect and analyze patient data from ECG ambulatory Transmitters/Transceivers, leading manufacturers' bedside monitors and ventilators anywhere in a healthcare facility and distributes the data to locations throughout the facility.

Performance Data:
The safety and effectiveness of the modified PatientNet™ Monitoring System described in this submission has been demonstrated through risk analysis and verification and validation testing. Test results demonstrated that the functionality and safety characteristics of the modified PatientNet™ Monitoring System are to the predicate device.

Conclusions:
Based on the information provided in this submission, the modified PatientNet™ Monitoring System is substantially equivalent to the predicate device and does not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2002

Ms. Diana M. Thorson
Regulatory Affairs Manager
GE Medical Systems Information Technology
General Electric Company
15222 Del Amo Avenue
Tustin, CA 92780

Re: K020524
Trade Name: PatientNet™ Monitoring System
Regulation Name: Arrhythmia Detector and Alarm
Regulation Number: 21 CFR 870.1025
Regulatory Class: Class III (three)
Product Code: MHX
Dated: February 15, 2002
Received: February 19, 2002

Dear Ms. Thorson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

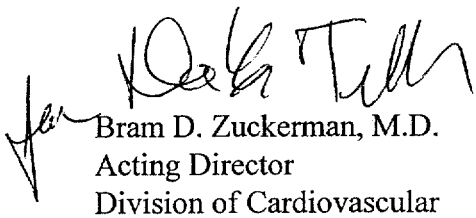
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K020524

Device Name: PatientNet™ Monitoring System

Indications for Use:

Monitoring of Recognized Conditions:
-An environmentally controlled clinical setting that has multiple patients using any combination of ECG leads, bedside monitors, or ventilators.
-Hospital areas that have the capability of installing hardwire paths to the Central Monitoring Station from the rooms or areas where bedside monitors or ventilators operate.
-Clinical areas that have the capability of installing 174-216 MHz radio systems (or alternate frequency bands approved by the FCC) to communicate via RF. The information from the ECG leads, bedside monitors or ventilators is transferred via an RF transmitter to the Central Monitoring Station.
Target Population:
Those patients who are connected through PatientNet™ Monitoring System via ambulatory ECG transmitters, bedside monitors, or ventilators.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020524

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)